ATTACHMENT B

TO
BASIC ORDERING AGREEMENT
ATTACHMENT 1
STATEMENT OF WORK

INITIAL/CONTINUING
LABORATORY
ASSESSMENT

INITIAL/CONTINUING LABORATORY ASSESSMENT

Criterion 1 -- Program

Each laboratory will provide services in accordance with DOE Order 414.1, “Quality Assurance,” The laboratory policies and approach to the implementation of DOE Order 414.1 must be formalized in a Laboratory Quality Assurance Plan (LQAP). The LQAP is a statement of the laboratory’s policies and approach to the implementation of DOE Order 414.1 for ensuring the generation of quality data. The LQAP will be forwarded for review to the ICPT National Agreement as one of the qualification requirements of the Analytical Support Agreement. Deficiencies or deviations from the requirements listed below *will* be identified by the Contractor in written correspondence to the Subcontractor. The laboratory must correct all deficiencies prior to the beginning of any analysis associated with the agreement. Corrections may be in the form of a revised LQAP, attachments or addenda to the LQAP, or a written response outlining the deficiency and the corrective action to be implemented by the laboratory. All changes or plans of action must be in effect before approval will be granted.

The LQAP shall define the organization's policies regarding, and its commitment to, ethical standards, client confidentiality and the implementation of safety and quality standards.

- Senior management shall be responsible for establishing the scope of the LQAP and implementing, assessing, and continually improving an effective quality system.

- Line management shall be responsible for achieving quality in specific activities.

- A designated individual shall be responsible for developing, implementing, and routinely monitoring the LQAP.

- All personnel, including samplers, field analysts, laboratory technicians, scientists, researchers, principal investigators, operators, craftspeople, clerical/support staff, and internal auditors shall retain responsibility for the quality of their work.

- Regulatory actions toward the organization or its parent corporation shall be reported immediately to cognizant management and affected clients. This includes actions, such as suspension of contracts with other Federal agencies, notices of investigations, and legal actions against the organization or its personnel.

- Functional responsibilities shall include the following activities as a minimum:

  - Participating with the client for planning and developing analytical work scope
  - Training and personnel development
  - Preparing, reviewing, approving, and issuing instructions, procedures, schedules, and procurement documents
  - Identifying and controlling hardware and software
  - Managing and operating facilities
  - Calibrating and controlling the equipment used to measure and test
  - Conducting investigations and improving methods
  - Acquiring, evaluating, and reporting data
  - Performing maintenance, repair, and improvements
  - Controlling records.

QA and/or QC positions shall report to the highest level of management (e.g., manager or director). The QA program shall identify positions given the responsibility and authority to do the following:

- Stop unsatisfactory work. The plan shall identify the chain of command through which any employee may initiate a stop-work order where detrimental ethical, contractual, quality, safety, or health conditions exist

- Initiate action to prevent reporting laboratory results from a measurement system that is out of control

- Prevent further reporting of measurements until corrective action has been completed

- Identify any method or procedure that poses quality problems

- Recommend, initiate, or provide solutions through designated channels, and monitor effectiveness of corrective actions.

Criterion 2 -- Personnel Training and Qualification

The Laboratory organization shall be clearly structured with well-defined responsibilities for each individual in the management system. This system shall ensure that sufficient resources are maintained to perform the requirements of the SOW.

Personnel performing services specified by the Statement of Work and personnel performing quality assurance activities shall receive suitable and timely indoctrination and training in such things as technical skills, laboratory analytical methods, QC procedures, safety policies, and waste management practices and essential elements of the QA Program prior to performing work. Such indoctrination and training shall be commensurate with the scope, complexity, and nature of:

(a) the services specified in the Statement of Work;
(b) the quality assurance activities specified herein; and
(c) the education, experience and proficiency of the person.

Records of the indoctrination and training shall take the form of:

(a) attendance sheets;
(b) training logs;
(c) personnel training records; and
(d) a description of the training and indoctrination.

The Laboratory shall have an internal analyst proficiency evaluation policy that provides a means to gauge and document the continuing competence of experienced individuals, as well as specifying additional training and documentation practices applicable to all personnel.

Laboratory personnel in management and supervisory roles shall have a formal education with a minimum of a BS or BA degree in chemistry or a related science and 2 years experience. The Laboratory Manager/Director shall have a minimum of a BS or BA degree in chemistry or a related science and 5 years experience. Program managers, computer scientists, health physicists, industrial hygienists, and quality assurance officers shall be selected based on documented qualification criteria for education, training, and experience. Laboratory technicians and analysts shall be fully trained to the laboratory procedures and instruments with which they are involved. The laboratory shall provide written documentation to support qualifications of personnel. At the client's discretion, experience may be substituted for degrees on a case-by-case basis. All persons working with or for the laboratory shall have the appropriate state and federal certifications necessary to perform their job duties.

An appendix shall be included that lists all personnel, their assignments and responsibilities,

degrees of education, and the years of applicable experience. This information may be supplied in the form of resumes. Any education and training related to tasks performed for this statement of work shall be listed.

Criterion 3 -- Quality Improvement

A system shall be established and implemented to identify, document, correct, and prevent quality problems, and this system shall be subject to ongoing documented review by management to assess it's effectiveness. Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction shall include identifying the causes of problems and working to prevent recurrence. Item reliability, characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items, services, and processes needing improvement. Examples of conditions where some level of corrective action is required are as follows:

- Documentation errors
- Diverse trends in the analysis of standards
- Failure to follow client analytical requests
- Failure to comply with approved technical and administrative procedures
- Failure to follow the preventive maintenance program
- Failures in the instrument systems or malfunctions in field equipment
- Failures in performance evaluation sample analysis audits, and assessments
- Validation and/or verification issues negatively impacting reported results
- Recurring adverse problems, including "near-miss" problems, such as "outside of warning limits," analysis blank problems, and other adverse trends
- Misidentification or mishandling of samples.

Management shall be responsible for problem investigations. The corrective action process shall include the following requirements: (1) determining the significance of quality problems, and (2) taking effective corrective action based on the potential impact on the data quality. Implementation of corrective action shall be verified. Corrective action shall be complete when the affected systems meet specifications. Measures to eliminate or minimize recurrence of quality problems shall be established. The corrective action process shall describe the provisions for determining the cause of nonconforming items and processes. The extent of analysis shall be commensurate with the importance or the significance of the problem (i.e., graded approach).

The corrective action process shall describe the provisions for determining if corrective actions have not been effective in preventing recurrence of quality problems. Preventive action shall be initiated, as appropriate, considering the magnitude of potential problems. When preventive measures are implemented, their effect shall be monitored to ensure that desired quality objectives are satisfied and maintained.
Provisions for making corrective action determinations shall include but not be limited to the following:

- Determining the events leading to the adverse condition
- Determining the technical and work activities associated with the quality problem
- Ascertaining the quality problem's generic implications
- Determining the extent to which similar quality problems (or precursors to the problem) have been recognized
- Determining the effectiveness of any corrective actions that were taken
- Determining the impacts on the completed work
- Recommending actions that can be taken by the responsible organization to preclude recurrence
- Determining if stopping the work associated with the activity is necessary.

The corrective action process shall describe provisions for analyzing quality-related information to identify trends that adversely impact quality and opportunities to improve items and processes. Analysis of quality-related information shall include, where possible, identifying common work processes for item quality problems, conducting cause-and-effect analysis, and determining effective corrective and preventive actions from external sources.

Quality-related information to be analyzed shall include, but not be limited to, the following:

- Performance data
- Audit reports
- Surveillance reports
- Nonconformance reports
- Failure rates
- Quality-related information from external sources
- Performance indicators.

Trend analysis shall be performed in a manner and at a frequency that identifies significant quality trends, and evaluates them for timely and appropriate corrective action. Trends determined to be adverse to quality shall be reported to the organization(s) responsible for corrective action.

Controls shall be implemented for samples/materials, parts, or components that do not conform to requirements in order to prevent their inadvertent use. These measures shall include, as appropriate, procedures for identification, documentation, evaluation, segregation (where practical), disposition, and notification to affected organizations.

Out-of-Control occurrences shall be documented and the person responsible for correction, documentation, and follow-up action. Examples of out-of-control events and corrective action include:

Structural flaws in electronic data package deliverables.

- Corrective actions at the receiving level. For example, a sample is broken during transport. The occurrence is documented on an out-of-control form.
- Corrective actions include immediate notification of the client to determine the follow-up action based on project needs.

- Observations corrected at the bench. For example, calibration of an instrument is not linear. The analyst discovers this and corrects the problem before continuing sample analysis. The laboratory shall document this, note that the corrective action was to recalibrate, and document that no samples were affected.

- Corrective action taken by analyst. For example, a semi-volatile organic analysis sample exhibits matrix problems or is damaged. The analyst shall request re-extraction by submitting a written reanalysis request form or comparable documentation to the preparation laboratory.

- Corrective actions taken by supervisor. For example, a Matrix Spike (MS) recovery is out-of- control, and the laboratory supervisor discovers this after samples have been analyzed. The supervisor shall document the occurrence and the corrective actions taken.

Criterion 4 -- Documents and Records

Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings that include quantitative or qualitative acceptance criteria that can be used to determine whether activities are satisfactorily accomplished. Revisions to instructions, procedures, and drawings that affect the process or are technical in nature shall receive the same level of review and approval by the affected parties as the original document. Editorial changes may be made to instructions, procedures, and drawings without review and approval. Document control shall include measures by which documentation can be controlled, tracked, and updated in a timely manner to ensure that applicability and correctness are established. Control measures shall be used to ensure that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location of the prescribed activity.

The laboratory policy and its implementation shall ensure that controlled copies of analytical procedures and that Standard Operating Procedures (SOPs) are available to the analyst.

A discussion of data evaluation procedures for each analytical method, as well as for an entire data set shall be included. The process for data review and approval shall be outlined as well and the person with authority to release the data shall be identified.

Measures shall be taken to ensure that users understand the documents to be used. Obsolete or superseded documents shall be identified, and measures shall be taken to prevent their use, including removal from the work place.

Additionally, a system shall be established and implemented for identifying, preparing, approving, transmitting, correcting, distributing, retaining, retrieving, and disposing of quality records. These systems shall ensure that records are maintained and controlled in a manner that facilitates retrospective review of all aspects of work performed to produce a reported result. These system(s) shall be subject to ongoing review by management to assess their effectiveness.

Documents designated to become quality records shall be legible, accurate, complete, and appropriate to the work accomplished. Corrections to documents that will become quality records shall be made by drawing one line through the error, initialing and dating the error, and justifying the correction (if not self-explanatory). Changes to computerized data records shall be identified such that original and corrected entries are retrievable and the individual initiating the changes can be identified.

A procedure delineating the records control system shall be established. This procedure shall include the following:

- Specifications of items, data, and processes of which records are to be controlled
- Requirements for the preparation, review, approval, and maintenance of records to accurately reflect completed work and to fulfill statutory requirements
- Requirements and responsibilities for record transmittal, distribution, change, retention, protection preservation, traceability, archival, retrieval, and disposal
- Verification that records received are legible and are in agreement with the transmittal document
- Requirements for access to and control of the files
- Procedures for the control, and client confidentiality accountability of records removed from the storage location
- Procedures for filing of supplemental information and disposing of superseded records
- Storage of records in a manner approved by the organizations responsible for the records
- Replacement, restoration, or substitution of lost or damaged records
- Procedures for data correction, which include how corrections are to be made and establish who is authorized to change or correct data.

Records shall include documents such as operating logs, results of reviews, inspections, tests, assessments, monitoring of work performance, material/sample analyses, calibration records and sub-contractor evaluations/results. Records shall also include closely related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall include, as a minimum, the identification of the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken to correct any deficiencies noted.

Criterion 5 -- Work Processes

Work shall be performed to established technical standards and administrative controls. Work shall be performed under controlled conditions using approved instructions, procedures or instructions. Analytical procedures shall be listed by method number and matrix. Any method variances employed by the laboratory shall be documented. The laboratory shall specify protocols for reporting any incident that delays sample processing for a period of time, affects holding times, or delays work, and also specify the corrective action implemented. Examples of forms used to document out-of-control events are to be provided in the LQAP.

Documentation for Environmental Protection Agency (EPA) method variance approvals shall be presented. A listing of the typical method-detection limits achieved for water, soil, and other matrices commonly analyzed by the laboratory shall be included. It is understood that these may vary with individual samples; however, procedures for determining limits of detection and the frequency of verification shall be outlined.

Analysis of QC Samples and Documentation -- A summary of QC procedures and documentation to be employed in the day-to-day operation of the laboratory shall be included. The discussion will emphasize the following as they relate to the different QC levels:

- Analysis of method and reagent blanks
- Analysis of duplicates, spiked samples, spiked laboratory blanks, and reference or control standards such as EPA check standards;
- The criteria used to establish warning and control limits for the above types of QC samples;

- Documentation and examples of control data and control charts;
- The frequency of analyzing blanks and other QC samples;
- How data from QC samples are reported and reviewed; and
- Who reviews and makes decisions relative to QC data.

The LQAP shall include a listing of approvals from other agencies and states.

Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained. The LQAP shall include the laboratory's definition of accuracy, precision, completeness, and representativeness. The method for evaluating measured parameters and data sets for accuracy, precision, completeness, and representativeness shall be incorporated.

As required by the specific analytical methods, reagent grade or higher purity chemicals shall be used. Reagents shall be checked prior to use and the supporting documentation of the checks shall be filed in a manner that can be easily retrieved. All standards and reference materials shall be traceable to a nationally recognized or consensus source. Preparation of standards, including any dilutions, shall be documented in a logbook. All standards shall be assigned a unique identification number traceable to the original standard. The certificates of authenticity shall be kept on file for all standards and reference materials. Each laboratory shall develop and implement a SOP specifying the policy for the shelf life, labeling, and re-certification of reagents and stock solutions. The shelf life of all standards, reagents, and reference materials shall be labeled on the individual containers and their status tracked. Standards and reference materials shall be stored separately from samples and standards protected in a controlled cabinet or refrigerator. Organic standards shall be properly refrigerated and stored as required by the specific analytical method. Stock solutions or standards that are kept for long periods shall be frequently checked for stability against quality control samples. These checks shall be documented in a logbook.

Criterion 7 -- Procurement

A process shall be established and implemented to control purchased items and services; this process shall be subject to ongoing review by management to assess its effectiveness.
Contract documents shall require that suppliers of all tiers comply with technical and quality assurance requirements, including but not limited to, standards, measuring and test equipment, calibration services, and analytical test activities. Contracted items and services that have the potential to affect the quality of analytical tests shall be controlled to ensure conformance with contractual requirements. Such control shall include one or more of the following: Source evaluation and selection (pre-performance/pre-award survey) source verification, audit, and examination of items or services before use.

Provision shall be made in all contract documents for audit of supplier and subcontracted quality systems by the client. Procured items and services shall meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria.

Procurement system controls shall make provision for the following:

- Identify applicable technical and administrative requirements from this Statement of Work for contracted services and items including acceptance criteria.

- The process for selecting and qualifying subcontractors

- Establishing processes to ensure that qualified subcontractors continue to provide acceptable products and/or services
- Accepting purchased items and/or services
- Receiving and maintaining procurement records, including evidence of conformance
- Documenting nonconforming items and services.

The procurement documents shall specify the quality system elements for which the supplier is responsible and how the supplier's conformance to the customer's requirements will be verified. Procurement documents shall be reviewed for accuracy and completeness by qualified personnel prior to release. Changes to procurement documents shall receive the same level of review and approval as the original documents.

When there are indications that subcontractors knowingly supplied items or services of substandard quality, this information shall be forwarded to appropriate management for action (e.g., subsequent reporting to the DOE Office of the Inspector General).

Criterion 8 -- Inspection and Acceptance Testing

Inspection and acceptance testing of specified items, services and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspection and tests shall be calibrated and maintained. There shall be a current list of available (on hand) equipment types, models, and years and a general description of the facility. General information shall be included as to who performs major, preventative, and day-to-day equipment maintenance and how it is documented. A schedule of preventive maintenance activities shall be developed and the performance of preventive maintenance shall be documented. A documented inventory of critical spare parts and/or equipment necessary to minimize the downtime of measurement systems related to analytical test samples that have a holding time of 48 hours or less shall be maintained. A documented evaluation of the usage of such inventory shall be performed at least annually. Control processes shall be maintained for all instrument spikes, replicates/splits, blanks, and other standards.

The laboratory shall produce control processes on a frequency sufficient to provide full data interpretation. The laboratory shall perform data quality checks prior to transmitting data.

Data check computer program, or similar logic, shall be used by the laboratory to assure error free data transmittal. Calibration procedures shall be listed by instrument type.

Procedures shall be defined for ensuring that balances, refrigerators, ovens, and other laboratory equipment are accurate and that their performance is monitored and documented.

Balances shall be checked each day that they are used and shall be calibrated at least annually by an independent company or source.

Refrigerator temperatures shall be monitored daily.

Measuring and test equipment used for activities affecting the quality of analytical tests shall be calibrated, adjusted, and maintained at prescribed intervals or prior to use against certified equipment or standards having known and valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration shall be documented. Each calibration procedure shall specify the standard to be used, the required frequency of calibration, any special instructions necessary for obtaining reliable calibration data, calibration control limits and the required treatment of data. The calibration and control of standards required for any analytical test shall be specified in the

analytical test procedure and in the calibration and control procedures if they are separate from the analytical procedure. Tolerances for all measurements made during performance of an analytical test shall be specified. If a tolerance limit is not stated with a measurement value, then a system of tolerances shall be specified. When measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented of the validity of any previous analytical test results obtained using that equipment during the relevant period. The results of such evaluation shall be promptly reported to the affected client. Out-of-calibration equipment shall be tagged or segregated and not used until it has been recalibrated. If any measuring or test equipment is consistently found to be out of calibration, it shall be repaired or replaced. A calibration shall be performed when the accuracy of equipment is suspect. Measuring and test equipment shall be properly handled and stored to maintain accuracy. Records of calibration activities shall be maintained and all calibrated equipment shall be suitably marked to indicate calibration status.

Criterion 9 -- Management Assessment

A method shall be established whereby management with executive authority assesses the adequacy of the quality assurance program at least annually to ensure its continuing suitability and effectiveness in satisfying the requirements of this SOW and the supplier's stated policies and objectives. The method shall include provisions for reporting the results of management assessments, including the distribution of those reports. Problems that hinder the organization from achieving its objectives shall be identified and corrected.

Criterion 10 -- Independent Assessment

Designated persons or organizations shall be responsible for ensuring that an appropriate Quality Assurance program is established and for verifying that activities affecting the quality of the services specified in the Statement of Work have been correctly performed. Such person or organization shall have sufficient authority, access to work areas, and organizational freedom necessary to independently assess all activities affecting quality and to report the results of such assessments. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed. Assessment results shall be documented, reported to and reviewed by the level of management with authority to affect any necessary corrective actions. . Assessments shall be conducted of subcontractors that perform work affecting the integrity of analytical results and to assure continued conformance to contractual requirements.

Special QA Requirements

A. Software Control

1. Software Documentation - Systems design interface and Software Development Life Cycle (SDLC) documentation shall be required for each computer program that (1) is capable of being tested and evaluated independently and (2) is a part of a software system affecting the quality of analytical tests. Software design shall (1) depict top-down structured development with major modules satisfying an identifiable contract requirement and (2) be approved by management and quality assurance personnel prior to use. Program development will depict a top-down structured format with data flow and program control being identifiable and traceable. Program modules will be traceable to the applicable software design requirement. Original Equipment Manufacturer (OEM) provided software which are not modified are exempt from the requirements of this paragraph.

2. Software Testing - Verification of computer programs affecting the quality of analytical tests shall be performed and documented. Test requirements and acceptance criteria shall be estimated prior to testing. Software verification testing shall be performed by qualified individuals that are not part of the development effort or who report to the Contractor's Manager responsible for software development. Models, methods, assumptions, and the computer environment which are used in the test shall be identified and documented. OEM provided software packages which are not modified shall be verified by using data for which the correct results are known.

3. Software Control - Configuration Management methods shall be established to ensure that changes to computer software which affect the quality of analytical tests are properly controlled and approved. Analytical test results shall be traceable to the version(s) of software used in the analysis, data collection, evaluation and/or reporting of test results.

4. Security of Software - Policy and procedures shall be established which will ensure the security of the software affecting the quality of analytical test results. This includes the loss and the unauthorized use of the computer software. Both software and electronic data shall be backed up at a documented frequency. The frequency of backup shall be based on the amount of data and the impact of the loss of data or software on the organization.

5. Error Control - Policy and procedures shall be established to evaluate, control, and correct data entry errors or program problems which affect the quality of analytical test results. Software errors found during use shall be reported to the appropriate level of management. In the case of field/laboratory-developed software, personnel shall be assigned to verify all errors and document the error notification and all corrective actions. Error handling shall include all users so that previously reported data may be evaluated and corrective actions may be tracked.

B. Sample Preparation.

1. Sample glassware and containers shall be either designated as disposable or cleaned according to recommended procedures that are listed in the individual Analytical Master Specifications.
2. A copy of the laboratory-specific Standard Operating Procedure (SOP) for glassware shall be posted in the glassware cleaning area. The sample preparation areas shall be kept clean to avoid contamination or cross-contamination.
3. To monitor for contamination during refrigerated storage, a refrigerator storage blank shall be required for the storage of all volatile organic samples. Specific procedures for

assessing the adequacy of these storage blank data and taking action for nonconforming conditions shall be established. The refrigerator storage shall be analyzed every 14 days when samples are being stored in the laboratory. The data from the analysis of the refrigerator storage blanks shall be available for review. If required by the Statement of Work, a refrigerator storage blank will be required for the storage of mercury and tritium samples with elevated levels of contaminants.

4. Water used to prepare reagents, standards, samples, and solutions shall be routinely (as a minimum quarterly) monitored for purity and documentation of the checks shall be maintained. The conductivity of the water from the purification system shall be monitored daily upon use, and the result shall be documented. Water used for organic analysis shall meet the requirements for organic-free water as required by the specific methodologies. Each laboratory shall develop and implement a SOP for reagent and de-ionized water production. The SOP shall include the preventive and routine of the water purification unit. The SOP shall include the specific control criteria for reagent and de-ionized water and the corrective actions to be taken in the event of an out-of-control event.

C. Quality Control

1. Each laboratory shall ensure, for each analytical method, that a means is established to measure contamination levels, method accuracy, method precision, interferences, and loss of an analyte during preparation. These objectives shall be accomplished through instrument calibration with traceable standards and the evaluation of quality control sample analyses.
2. Each preparation batch, as applicable, shall contain a method blank and a Laboratory Control Sample (LCS) (QC check sample). In addition, the organic preparation batches shall include a matrix and a matrix spike duplicate.
3. Radiochemistry and inorganic preparation batches shall contain a duplicate and a matrix spike.
4. ICP analysis shall include an inter-element check standard. The LCS shall be prepared from an independent source. The spikes shall be carried through the entire analytical process.
5. Primary standards shall have traceable documented certificates of accuracy and/or purity. Procedures shall be developed for the review and acceptance of QC sample results, including established limits for which data shall be reviewed against. Statistical control methods shall be maintained for accuracy and precision. Acceptability of QC samples to performance criteria shall be checked as soon as possible after data generation, and these checks shall be documented. Corrective actions shall be established for QC sample results that exceed the control limits.
6. To evaluate contamination, precision, and accuracy of an analytical system, QC samples shall be used as appropriate. A method blank, or reagent blank, shall be carried through the complete sample preparation and analytical procedure. A duplicate shall be an intra-laboratory split sample and shall be used to document the precision of a method. The laboratory shall employ, reference materials, matrix spike samples, tracers, surrogates, interference checks, and calibration checks to measure some component of accuracy.

D. Statistical Control Methods

1. Each laboratory shall develop and implement statistical control methods. Statistical control methods shall be developed and used in a real-time manner. The control methods shall be accessible to the individual performing the analyses, data reviewers, and to the quality assurance staff.
2. The laboratory shall provide a brief description of the basic methodology for control methods.

E. Good Automated Laboratory Practices (GALP)

1. Principles of the Good Automated Laboratory Practices (GALP) shall be used by the laboratories to ensure the reliability of data. These include traceability, accountability, standardized procedures, adequate resources, and the availability of documentation for conformance to the requirements.
2. When the LIMS or equivalent system is used to collect, analyze, process, or maintain raw data, laboratory management shall ensure that:

- personnel clearly understand the function(s) they are to perform and have adequate education, training, and experience to perform assigned functions.
- personnel, resources, and facilities are adequate and available as scheduled.
- corrective actions are promptly taken in response to any deficiencies reported from assessments of the system.
- procedures have been written, reviewed, approved and implemented to the GALP criteria
- development methods are based on the size and nature of software being developed and in accordance with the EPA Information Resources Management Policy Manual, Chapter 17.

F. Sample Control and Building Security

1. Physical or administrative controls shall exist to ensure that Chain of Custody (COC) is not broken during times that laboratory staff are present.
2. Physical control shall exist in all laboratory areas to ensure that sample COC is not broken during periods when laboratory staff are not present. Visitor access is controlled by positive administrative controls and strict escort rules shall be developed for all visitors. The facility shall have controlled entrance and egress points.

G. Specific Laboratory Requirements

To participate in the agreement, each laboratory must provide evidence of compliance with all the criteria listed below:

1. Establishment of a Decontamination & Decommissioning (D&D) Financial Assurance Plan, including funding provisions.

   Evidence of financial assurance sufficient to disposition all sample residues and laboratory wastes and decommission the facility per requirements of the Nuclear Regulatory Commission (NRC) or Agreement States.

2 Participation in the Performance Evaluation (PE) Programs

   The laboratory must demonstrate successful participation for a minimum of one year in nationally recognized PE programs, and must pass the criteria of the program. Any individual analyte failures must be corrected within the next PE program performance cycle period. Consecutive failures of the same analyte will be considered unsuccessful participation for that analyte. The purpose of the PE sample analysis is to gauge the proficiency of each laboratory's methods by providing samples of relatively homogenous blend and known analyte concentration. These PE programs include:

a. Water Pollution (WP) Laboratory PE operated by the Environmental Protection Agency (EPA) National Exposure Research Laboratory in Cincinnati, Ohio (NERL-Ci).

b. Water Supply (WS) Laboratory PE operated by the National Exposure Research Laboratory - Cincinnati, Ohio (NERL-Ci).

c. PE Studies Programs for Radioactivity measurements, operated by the EPA Center for Risk - Las Vegas, formerly known as EMSL - Las Vegas (EMSL-LV) or their replacement.

d. Environmental Measurements Laboratory (EML) QA Program operated by DOE Environmental Laboratory (EML) in New York, New York, for Radioactivity measurements.

e. Quarterly Blind (QB) PE, operated by EPA Office of Emergency and Remedial Response through EPA Center for Risk.

f. Mixed Analyte Performance Evaluation Program (MAPEP), operated by DOE Radiological and Environmental Science Laboratory (RESL) at Idaho National Engineering Environmental Laboratory (INEEL) site.

Analysis	Applicable PE(s)	Required/Recommended
Inorganic & General Chemistry (e.g., TDS, residual chlorine, oil and grease)	WP or equivalent WS or equivalent MAPEP *NELAP PT	Required Required Required
Metals	WP or equivalent WS or equivalent QB MAPEP *NELAP	Required Required Recommended Required Required
Organics	WP or equivalent WS or equivalent QB MAPEP *NELAP	Required Required Recommended Required Required
Radioactive Isotopes	EML EPA NERL or equivalent MAPEP	Required Required Required

*As Performance Testing (PT) materials become available.

In addition, the Contractor reserves the right to submit blind PE samples. Each laboratory must continue to participate in all applicable rounds of external PE programs. The results of all PE programs may be utilized by SMOs at the various ICPT National Agreement for Analytical Services Team sties in existing, comprehensive laboratory evaluation programs at that site. Examples of these programs are the Integrated Performance Indication Program (IPIP) at the Oak Ridge site and the Analytical Services Performance Evaluation Program (ASPEP) at the INEEL site. Additionally, results from these PE programs will be captured in the DOE National Analytical Management Program (NAMP)

Integrated Performance Evaluation Program (IPEP) database that will be available to all NAMP participants within DOE.

As the EPA Water Pollution (WP) and Water Supply (WS) programs are discontinued, each laboratory will be required to continue participating in relevant external performance evaluation program. A laboratory must participate in two single-blind, single-concentration performance testing (PT) studies per year. The single-blind studies must be related to regulatory or environmental programs, matrix types, or analytes for the analytical disciplines that each laboratory performs (i.e., Inorganic, Organic, Radiochemistry)

3. Possession of a current NRC License or Agreement State license and Radiological Material control.

   a. a. Laboratories providing analytical services to Contractors for samples that may contain induced radioactivity will have and maintain a NRC or Agreement State radiological materials license. This includes having a Radiological Control Plan and Radiological Receipt acceptance protocols/procedures. Personnel qualified/certified to ship and receive radiological material.

   b. Capable of receiving and analyzing samples that may contain manmade induced radioactivity (10CFR).

4. Waste Management Plan

   A waste management plan shall be submitted and reviewed by the ICPT Audit Team. This plan must be capable of identifying all waste streams generated by the laboratory, identifying the process for managing and disposition of the various waste streams, and tracking the disposition of the waste samples by Sample Data Group (SDG). The Waste Management Plan shall include, but not be limited to the following:

   a. Administrative Programs to demonstrate compliance for all effluent discharges as required by regulatory agencies.

   b. Training procedures, training schedule, and management of training records in the following areas: waste management, waste shipping, waste handling, and radioactive materials control.

   c. Radioactive volumetric and surface release policies.

   d. All applicable permits and licenses to handle hazardous and radioactive waste.

   e. Policy or direction on how to conduct waste brokering and Transport, Storage, and Disposal Facility (TSDF) evaluation to ensure proper dispositioning of wastes. Waste is defined as radioactive, hazardous and mixed materials, liquid effluents, and general non-regulated trash.

   f. Tracking of individual sample containers from receipt to final disposition.

5. Radioactive Materials Inventory

   The laboratory is required to have a radioactive materials inventory program capable of tracking standards, tracers, and all licensable samples. The emphasis of the plan is to effectively track and monitor, on a real-time basis, the radioactive materials within the possession of the laboratory against the specific quantities, isotopes, and types listed in

the radioactive materials license. The laboratory will be required to demonstrate that this program ensures that the radioactive materials license will not be exceeded.

6. Environmental, Safety and Health Planning

The laboratory must be able to demonstrate compliance or exempt status with the environmental, safety and health requirements of applicable laws, regulations, and standards. The applicable regulatory requirements include those by the Occupational Safety and Health Administration (OSHA), DOE, EPA, NRC, and Department of Transportation (DOT), and/or their State or Local counterparts.

7. Hard Copy Notebooks

The laboratory shall maintain hard copy laboratory notebooks that detail the sample bottle preparation and analytical work, including the analyses being performed, samples being analyzed, procedures used, reading taken, calculations performed, analytical results, and any observations during analysis. These notebooks must follow EPA guidance and be filed at the laboratory so that these notebooks will be available for audits.

8. Standard Operating Procedures

A standard Operating Procedure (SOP) is defined as a written narrative description of facility procedures including examples of laboratory documents. The laboratory shall have written SOPs covering, but not limited to, the following areas:

- Sample tracking and COC (from receipt to disposition)
- Sample preparation (including subsampling)
- Sample storage and security
- Proper sample disposition
- Prevention of sample contamination
- Facility security
- Data reduction, verification, and reporting
- Acceptance criteria (e.g., QC limits, calibrations, etc.)
- Document control
- Data packages review prior to submittal
- Shipment of deliverables
- Records disposition
- Preparation and traceability of standards
- Catastrophic failure of a refrigerator, freezer unit
- Glassware cleaning
- Equipment maintenance
- Qualification of personnel and training

A formal quality assurance checklist will be used for the performance of at-site audits.